

REMARKS/ARGUMENTS

Claims pending in the case are: 1-2, 4-19, 27-49. Claims 6-11 and 27-43 were withdrawn from consideration as being drawn to a non-elected invention. Claims 46-49 were newly added claims to a food supplement, which the examiner now withdraws as not within the elected species.

Claim 2 is amended wherein the S-equol is substantially from a racemic mixture of S-equol and R-equol.

Scope of the Subject Matter

The Examiner withdrew Claims 46-49 as being drawn to a non-elected invention. The Examiners states that the inventions of Claims 46-49 are patentably distinct from the elected subject matter as it differs in structure and element and would require separate search consideration. In addition, a reference, which anticipates one group, would not render obvious the other.

Applicants traverse the withdrawal of Claims 46-49, and request reconsideration.

Claim 46 is directed to a food supplement for use in making commercial products, consisting essentially of S-equol. Claim 1, by comparison, is directed to a composition for use in making commercial products, consisting essentially of S-equol.

Though these claims may be patentably distinct, the Examiner has not shown, and reasonably can not show, that the two claims/inventions have materially different structure or elements. Furthermore, there is considerable overlap between the claims. Applicants also refute that the additional claims would require excessive additional searching.

Reconsideration of the Examiner's withdrawal, and reinstatement, of Claims 46-49 is requested.

Rejections under 35 USC 103(a)

Claims 1-2, 4-5, 12-17, 19, 44 and 45 are rejected as obvious over Gorbach US 6,060,070. The rejection states that Gorbach discloses compositions containing equol for use in making commercial products and food compositions such as confectionary bars, cereal, biscuit, beverage or medicament, as well as a method of treating aging using equol.

i. The rejection states that "the difference between the prior art of Gorbach and the instant

claims is that in the prior art the racemic mixture is disclosed, while the s enantiomer is in the instant application.”

ii. The rejection goes on to state that “in the absence of showing unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with Gorbach to make useful commercial products and food compositions, selecting one of the isoflavonoids Gorbach disclosed.

iii. The rejection further states that “a stereoisomer is not patentable over its known racemic mixture unless it possesses unexpected properties not possessed by the racemic mixture”, and references *In re Anthony*, 162 USPQ 594, 596 (1969) and *In re Adamson*, 125 USPQ 233, 234 (1960).

iv. The rejection also states that “the MPEP 2112 states the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 USC 102 or 103. Something which is old does not become patentable upon the discovery of a new property”, and references *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

Applicants traverse.

i). Gorbach can not be relied upon to show that equol is a racemate

Gorbach '070 teaches treating aging skin disorders by administering isoflavonoids. Included in a long list of such isoflavones is equol. Gorbach states that isoflavones are “found in soy beans...red clover, and in lower amounts in many other types of plants.”, and that “isoflavones are also available commercially in substantially pure form.” Technically, equol is not an isoflavone, and it is not naturally occurring in plants.

Gorbach only mentions “equol”. Gorbach also does not specify the form of the equol. The Examiner presumes that Gorbach discloses a racemic mixture of equol, but provides no evidence in the rejection. There is no prior art in the record that establishes that a person of ordinary skill in the art would know that equol is a racemate. The rejection therefore fails to establish *prima facie* obviousness because the Examiner has not established that a person of ordinary skill in the art would understand from Gorbach that equol is a racemate.

ii). Gorbach is not enabling for the use of “equol” in commercial products

Gorbach mentions the word “equol”, but provides no commercial source of equol, either by extraction from plants or other “commercially available” source. Gorbach is a reference “only for what is disclosed in it”, (See Reading & Bates Constr. Co. v. Baker Energy, 748 F.2d 645, 652, 223 USPQ 1168, 1173 (Fed. Cir. 1984)), and fails to disclose a commercially available supply, or any means of making or obtaining a commercially available supply of equol, be it racemic equol or an enantiomer of equol.

Furthermore, Applicants are not aware that a commercially available supply of equol existed at the time that Gorbach issued, or prior to Applicants’ filing date, particularly in a purified form.

Rejection over Gorbach in view of Miller

The Examiner also rejects claims 18, 44 and 45 under 35 USC 103(a) as obvious over Gorbach in view of Miller et al. (US 6,159,959). These claims cover conjugates of S-equol. The Examiner alleges that Miller teaches combining equol with 20-R-thiol-3-sodium sulfate forms a sulfate conjugate of equol.

Applicants traverse.

i). Gorbach can not be relied upon to show that equol is a racemate. As asserted above, the rejection fails to establish *prima facie* obviousness because the Examiner has not established that a person of ordinary skill in the art would understand from Gorbach that equol is a racemate.

ii). Gorbach is not enabling for the use of “equol” in commercial products

As asserted above, Gorbach fails to disclose a commercially available supply, or any means of making or obtaining a commercially available supply of equol, be it racemic equol or an enantiomer of equol.

iii) Neither Gorbach nor Miller disclose or suggest C-4’ or C-7 conjugates of equol as provided in Claims 18, 44 and 45.

Miller discloses a composition comprising an estrogen and an anti-estrogen compound of

benzo[a]carbazoles or indenoindoles. Miller teaches that equol can be one of a long list of estrogens. Miller discloses nothing about the structure or commercial source of equol.

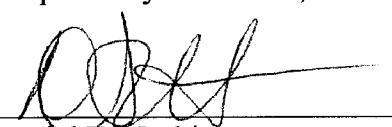
The Examiner appears to have concluded that, because "equol" in Claim 18 appears next to phrase "20R-triol 3-sodium sulfate", that Miller somehow is teaching "combining equol and 20R-triol 3-sodium sulfate". The Examiner appears to have misread Miller. It seems more likely that the "20R-triol 3-sodium sulfate" is part of a compound "5alpha-Pregnan-3beta, 16alpha, 20R-triol 3-sodium sulfate", preceding the word "equol" in Claim 18.

The Examiner also makes the statement "the prior art discloses mixtures using equol and specific glucuronide, sulfate, etc.... groups." No such prior art is however cited. The Examiner also states that "it is well known in the art that equol is usually substituted at the C-4' and C-7 positions because that is where the hydroxyl groups are in the compound." Again, however, no prior art to this effect is cited, nor would such prior art necessarily correct other defects in the rejection.

Applicants believe a full and complete response to the Action has been made. Applicants request reconsideration and withdrawal of the rejections, and allowance of all claims.

Respectfully submitted,

By:



Daniel F. Nesbitt
Attorney for Applicants
Registration No. 33,746
(513) 229-0383
Customer Number 38155

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